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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,879	10/12/2005	Terrence R Langford	122123.00004US1	4467
34283 7590 12/24/2008 QUARLES & BRADY LLP ONE SOUTH CHURCH AVENUE, SUITE 1700 TUCSON, AZ 85701-1621				
EXAMINER DELCOTTO, GREGORY R				
ART UNIT		PAPER NUMBER		
1796				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,879

Applicant(s)

LANGFORD, TERENCE R

Examiner

Gregory R. Del Cotto

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 20 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 20 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 14, 20, and 27 are pending. Claims 1-13, 15-19, 21-26, 28, and 29 have been canceled. Note that, Applicant's arguments and amendments filed 9/17/08 have been entered. Furthermore, at the outset, the Examiner would like to point out that in the Office action mailed 3/18/08, the instant claims were stated to be rejected under 35 USC 102(e) as being anticipated by Hitchems et al (US 6,468,953) in view of Kasting, Jr et al (US 5,368,815) which was an inadvertent error. The claims should have been rejected under 35 USC 103(a) as being unpatentable over Hitchems et al (US 6,468,953) in view of Kasting, Jr et al (US 5,368,815) which is evidenced by the obviousness statement contained in the rejection present in the Office action mailed 3/18/08, and the correction has been made below.

Objections/Rejections Withdrawn

The following objections/rejections as set forth in the Office action mailed 3/18/08 have been withdrawn:

None.

Priority

Note that, priority has been corrected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1796

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 20, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hitchems et al (US 6,468,953) in view of Kasting, Jr. et al (US 5,368,815).

Hitchems et al teach the formation of antimicrobial solutions formed by ozonating a liquid containing organic precursor molecules. After ozonation is complete, the ozonated liquid may be diluted with water or other solvent to form a use solution for contacting and cleaning a microbially contaminated surface or other medium. See Abstract. Additives to the solution may include antimicrobial agents such as peroxygen-type disinfectants including peracetic acid, etc. See column 11, lines 30-65. The ozonated solution has a water to a water/ozonated solution ratio of between 1 and 100. See column 4, lines 30-55. A variety of embodiments known to those skilled in the art are possible for the mixing chamber, particularly with reference to how ozone is introduced into the liquid. For instance, a venturi device, located in a side stream in fluid communication with the contacting chamber can be used in certain embodiments. Fluid flow can be diverted from the contacting chamber through the venture device wherein ozone is introduced. The ozonated liquid is subsequently returned to the contact chamber. Liquid circulation through the venturi enables ozone to be continuously added to the liquid containing the active biocide precursors. The contact chamber also contains a means of dispensing ozonated solutions, such as an outlet

port in fluid communication with a device for using the ozonated solutions to clean microbially contaminated surfaces. See column 12, lines 1-28.

The process of the invention incorporates a means to generate and dispense rinse water of high microbiological quality. Rinse water is generally applied as a final treatment step to remove solutions employed in the sanitation or cleaning processes. A suitable rinse solution can be made by directing ozone-enriched gas to a separate contactor chamber (i.e., tank), where the contactor contains an aqueous solution. Ozone is contacted with the water for a sufficient time to eliminate substantially all microorganisms from the water. The treated water is dispensed and directed to the item that has first been previously contacted with a cleaning or sanitizing solution. The disinfected rinse water removes excess disinfectant or cleaning agents. Moreover, the use of a rinse solution treated with ozone is preferably because ozone is a potent means of eliminating microorganisms from water and it decomposes rapidly without leaving a chemical residue. See column 14, lines 30-51.

The present compositions and methods of using the compositions are useful in the cleaning or disinfecting of equipment in the health care industries. Examples of items that can be disinfected include endoscope reprocessors, catheters, etc. See column 15, lines 12-30. Processes of the invention can be carried out automatically, where events such as addition of ozone to the liquid, dilution of the ozonated liquid, refilling treatment reservoirs, and contacting tanks, activating conduits, pumping fluids, introduction of additives, and formulation of use solutions may be performed using integrated timers, valves, electronic controls, relays and computer programs.

Hitchems et al do not teach the step of continuously adding ozone to rinse water by recirculating past a venturi, or a method of cleaning and sterilizing a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection as recited by the instant claims.

Kasting, Jr. et al teach an apparatus for supplying ozone-containing water for sanitizing articles, said apparatus being characterized by automatic recirculating operation of a captive water supply, said apparatus comprising a storage vessel arranged for supplying water to be ozonated for sanitation or articles, a means for injecting ozone into the supplied water, etc. See claim 1. The apparatus provides a pressure differential bypass line for providing a constant recirculating flow of ozonated water from a venturi directly to a water storage tank, bypassing the rinsing apparatus. Also included are a supply line to the rinsing apparatus and a diverted supply line for diverting flow back to the storage tank and bypassing the rinsing apparatus. The supply line and the diverted supply line have a normally closed solenoid valve and a normally open solenoid valve, respectively, for controlling the flow of ozonated water between them and maintaining and regulating pressure and volume of water for optimizing injection of ozone into the water and for maintaining ozone in the water.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to add ozone to rinse water stored in a tank by recirculation past a venturi in the process taught by Hitchems et al, with a reasonable expectation of success, because Kasting, Jr. et al teach the addition of ozone to rinse water stored in a tank by recirculation of the water past a venturi in a similar sanitizing process and

further, Hitchems et al teach the incorporation of ozone into rinse water stored in a separate tank in general and recirculation past a venturi would be desirable to one of ordinary skill in the art from a sanitation point of view due to the quick decomposition of ozone.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to sterilize a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection and providing a final rinse with ozonated filtered water stored in a tank as recited by the instant claims, with a reasonable expectation of success, because the broad teachings of Hitchems et al in combination with Kasting, Jr. et al suggest sterilizing a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection and providing a final rinse with ozonated filtered water stored in a tank as recited by the instant claims.

Note that, with respect to instant claim 27, the Examiner asserts that Hitchems et al teach an apparatus for decontamination of medical equipment and the Examiner asserts that this apparatus would include items and/or parts falling within the broad scope of a "chamber, a filter, a tray and a fill line" as recited by the instant claims which would desirably be flushed with ozonated water by one of ordinary skill in the art after cleaning the medical equipment to ensure disinfection and sterilization of the actual cleaning apparatus.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/32467 in view of Kasting, Jr. et al (US 5,368,815).

'467 teaches an apparatus for cleaning medical equipment comprising a supply of filtered water, a supply of ozonated water containing a predetermined concentration of water and means for delivering first a flow of filtered water over the surfaces of the equipment to be cleaned for a predetermined time followed by a flow of ozonated water over said surfaces for a predetermined time to disinfect the surfaces. See Abstract. The ozonated water is de-ionized prior to ozonating to the predetermined concentration. In the system, unozonated water was pumped through the system for 10 minutes and then ozonated water was pumped through the system for 6 minutes which achieves a high level disinfection. See page 6, lines 1-15. After the cycle, rinse water and ozonated water may also be flowed over the outer surface of the endoscopes to disinfect these as well. See page 7, lines 10-35. The apparatus comprises a means for filtering the tap water used in the process to provide a supply of filtered water.

Note that, the Examiner asserts that '467 teaches high-level disinfection and that it would have been obvious to one of ordinary skill in the art to run an endoscope through two or more cycles of high-level disinfection taught by '467 on instruments contaminated with hard to kill bacteria to ensure disinfection of the instruments. This type of disinfection which employs several cycles of disinfection is well known to those skilled in the art to thoroughly sterilize medical instruments or resterilize instruments immediately before use and would suggest rinsing an already cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims. Additionally, '467 teaches an apparatus for decontamination of medical equipment and the Examiner asserts that this apparatus would include items and/or

parts falling within the broad scope of a "chamber, a filter, a tray and a fill line" as recited by the instant claims which would desirably be flushed by one of ordinary skill in the art with ozonated water after cleaning the medical equipment to ensure disinfection and sterilization of the actual cleaning apparatus.

'467 does not teach the step of continuously adding ozone to rinse water by recirculating past a venturi or a method of preventing recontamination of a cleaned and high-level disinfected item comprising rinsing the cleaned and high-level disinfected item with water following by flushing the apparatus with ozonated water as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to add ozone to rinse water stored in a tank by recirculation past a venturi in the process taught by '467, with a reasonable expectation of success, because Kasting, Jr. et al teach the addition of ozone to rinse water stored in a tank by recirculation of the water past a venturi in a similar sanitizing process and further, '467 teaches the incorporation of ozone into rinse water stored in a separate tank in general and recirculation past a venturi would be desirable to one of ordinary skill in the art from a sanitation point of view due to the quick decomposition of ozone.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to prevent recontamination of a cleaned and high-level disinfected item comprising rinsing the cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims, with a reasonable expectation of success, because the broad teachings of '467 in combination with

Kasting, Jr. et al suggest preventing recontamination of a cleaned and high-level disinfected item comprising rinsing the cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims.

Response to Arguments

With respect to the rejection of the instant claims under 35 USC 103 using Hitchems et al in view of Kastings, Jr. et al, Applicant states that Kasting teaches the use of water that is so thoroughly and freshly ozonated that it effects sanitation of the article being rinsed while the instant claims do not expose an endoscope to freshly generated ozone in the final rinse of the equipment. In response, note that, the Examiner asserts that Kasting, Jr. et al is analogous prior art relative to Hitchems et al and that one of ordinary skill in the art clearly would look to the teachings of Kastings, Jr. et al to cure the deficiencies of Hitchems et al. Kastings, Jr. et al is a secondary reference relied upon for its teaching of adding ozone to rinse water by recirculating past a venturi. The Examiner asserts that one of ordinary skill in the art clearly would have been motivated to add ozone to rinse water stored in a tank by recirculation past a venturi in the process taught by Hitchems et al, with a reasonable expectation of success, because Kasting, Jr. et al teach the addition of ozone to rinse water stored in a tank by recirculation of the water past a venturi in a similar sanitizing process and further, Hitchems et al teach the incorporation of ozone into rinse water stored in a separate tank in general and recirculation past a venturi would be desirable to one of ordinary skill in the art from a sanitation or sterilization point of view due to the quick decomposition of ozone.

Further, note that Hitchems et al (primary reference) teach that rinse water is generally applied as a final treatment step to remove solutions employed in the sanitation or cleaning processes. A suitable rinse solution can be made by directing ozone-enriched gas to a separate contactor chamber (i.e., tank), where the contactor contains an aqueous solution. Ozone is contacted with the water for a sufficient time to eliminate substantially all microorganisms from the water. The treated water is dispensed and directed to the item that has first been previously contacted with a cleaning or sanitizing solution. The Examiner asserts that Hitchems et al teach a rinse solution containing ozone which is then dispensed to the item to be rinsed such that the item not exposed to freshly generated ozone as recited by the instant claims. Thus, the Examiner maintains that the teachings of Hitchems et al in view of Kastings, Jr. et al are sufficient to render the claimed invention obvious under 35 USC 103.

With respect to the rejection of instant claim 27 under 35 USC 103 using WO02/32467 in view of Kasting, Jr. et al, Applicant states that both Kasting, Jr. et al and '467 exclusively teach the use of freshly ozonated water which is different from the method as recited by the instant claims. In response, note that, the Examiner asserts, as stated above, that Kasting, Jr. et al is analogous prior art relative to '467 and that one of ordinary skill in the art clearly would look to the teachings of Kastings, Jr. et al to cure the deficiencies of '467. Kastings, Jr. et al is a secondary reference relied upon for its teaching of adding ozone to rinse water by recirculating past a venturi. The Examiner asserts that one of ordinary skill in the art clearly would have been motivated to add ozone to rinse water stored in a tank by recirculation past a venturi in the process taught

by '467, with a reasonable expectation of success, because Kasting, Jr. et al teach the addition of ozone to rinse water stored in a tank by recirculation of the water past a venturi in a similar sanitizing process and further, '467 teaches the incorporation of ozone into rinse water stored in a separate tank in general and recirculation past a venturi would be desirable to one of ordinary skill in the art from a sanitation point of view due to the quick decomposition of ozone. Further, note that, the specification provides no specific definition as to what is meant by "freshly generated ozone" and in the absence of such a definition, the Examiner asserts that this term will be given its broadest reasonable interpretation. The Examiner asserts that '467 suggest the use of a separate container for ozonated rinse water which is used to contact the equipment being cleaned and the application of the water from the container to the equipment would not expose the apparatus to freshly generated ozone as recited by the instant claims. Thus, the Examiner maintains that the teachings of '467 in view of Kastings, Jr. et al are sufficient to render the claimed invention obvious under 35 USC 103.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory R. Del Cotto/
Primary Examiner, Art Unit 1796

/G. R. D./
December 22, 2008